UNITED STATES DEPARTMENT OF COMMERC United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------|--|----------------------|---------------------|------------------|
| 10/539,756 | 04/14/2006 | Kenji Sasaki | P28062 | 5026 |
| 7055 GREENBLUM | 7590 12/12/2007 1 & BERNSTEIN, P.L.C . | | EXAMINER | |
| 1950 ROLANI | 1950 ROLAND CLARKE PLACE | | GUSSOW, ANNE | |
| RESTON, VA 20191 | | | ART UNIT | PAPER NUMBER |
| | | | 1643 | |
| | | | | |
| | | • | NOTIFICATION DATE | DELIVERY MODE |
| | | | 12/12/2007 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com pto@gbpatent.com

| | | Application No. | Applicant(s) | | | |
|--|--|--|---------------|--|--|--|
| Office Action Summary | | 10/539,756 | SASAKI ET AL. | | | |
| | | Examiner | Art Unit | | | |
| | | Anne M. Gussow | 1643 | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| 1)□ | Responsive to communication(s) filed on | | | | | |
| · | This action is FINAL . 2b)⊠ This action is non-final. | | | | | |
| '= | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | |
| ,— | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Disposition of Claims | | | | | | |
| 4)⊠ Claim(s) <u>1-21</u> is/are pending in the application. | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6) | 6) Claim(s) is/are rejected. | | | | | |
| 7) | Claim(s) is/are objected to. | | | | | |
| 8)🖂 | 8) Claim(s) 1-21 are subject to restriction and/or election requirement. | | | | | |
| Applicat | ion Papers | | • | | | |
| 9) The specification is objected to by the Examiner. | | | | | | |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority (| under 35 U.S.C. § 119 | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1 Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| Attachmer | nt(s) | | | | | |
| 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) | | | | | | |
| 3) 🔲 Infor | ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08) er No(s)/Mail Date | Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other: | | | | |

10/539.756

Art Unit: 1643

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

To have a general inventive concept under PCT rule 13.1, the inventions need to be linked by a special technical feature. The special technical feature recited in claim 1 is protecting a thiol group in a protein by adding a compound which has a disulfide bond in the molecule. In view of this Thompson (US PAT 5,130,418, issued July 14, 1992) reads on the claim. Thompson teaches treatment of basic fibroblast growth factor with organic disulfides. Therefore the technical feature recited in claim 1 is not special. Accordingly the groups are not so linked at to form a single general concept under rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1 and 5-18, drawn to a method for protecting a thiol group in a protein. Group II, claim(s) 2, drawn to a method for inhibiting polymerization.

Group III, claim(s) 3, drawn to a method for inhibiting modification of a protein.

Group IV, claim(s) 4, drawn to a method for inhibiting an exchange reaction of a thiol group.

Group V, claim(s) 19-21, drawn to a protein.

10/539,756 Art Unit: 1643

2. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: as set forth above, in view of the teachings of Thompson, the groups are not so linked as to form a single general concept under PCT Rule 13.1 because the technical feature of claim 1 is not special.

Groups I and V are related by product and method of using. Their shared technical feature is protecting a thiol group in a protein, but Thompson, et al. teach a method for protecting a thiol group by adding disulfides. Group II requires polymerization which is not required for Groups I and III-V. Group III requires inhibition of modification which is not required for Groups I, II, IV or V. Group IV requires inhibition of an exchange reaction which is not required for Groups I-III or V.

- 3. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:
 - (a) the inventions have acquired a separate status in the art in view of their different classification;
 - (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
 - (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

Application/Control Number:

10/539,756

Art Unit: 1643

Page 4

(d) the prior art applicable to one invention would not likely be applicable to

another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C.

101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete <u>must</u>

include (i) an election of a invention to be examined even though the requirement

may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing

the elected invention.

The election of an invention may be made with or without traverse. To reserve a

right to petition, the election must be made with traverse. If the reply does not distinctly

and specifically point out supposed errors in the restriction requirement, the election

shall be treated as an election without traverse. Traversal must be presented at the time

of election in order to be considered timely. Failure to timely traverse the requirement

will result in the loss of right to petition under 37 CFR 1.144. If claims are added after

the election, applicant must indicate which of these claims are readable on the elected

invention.

If claims are added after the election, applicant must indicate which of these

claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably

distinct, applicant should submit evidence or identify such evidence now of record

showing the inventions to be obvious variants or clearly admit on the record that this is

the case. In either instance, if the examiner finds one of the inventions unpatentable

Application/Control Number:

10/539,756 Art Unit: 1643

over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

10/539,756 Art Unit: 1643

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double

10/539,756

Art Unit: 1643

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne M. Gussow whose telephone number is (571) 272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow

December 4, 2007

LARRY R. HELMS, PH.D. SUPERVISORY PATENT EXAMINER